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II

110TH CONGRESS
2D SESSION

S. 3144

To amend part B of title XVIII of the Social Security Act to delay and reform the Medicare competitive acquisition program for purchase of durable medical equipment, prosthetics, orthotics, and supplies.

IN THE SENATE OF THE UNITED STATES

JUNE 17, 2008

Mr. BAUCUS (for himself, Mr. GRASSLEY, Ms. STABENOW, Mr. VOINOVICH, Mr. SALAZAR, Mr. ROBERTS, Mr. BROWN, Mr. SMITH, Mr. CASEY, Ms. COLLINS, Mr. LEVIN, Mrs. DOLE, Mr. LIEBERMAN, Mr. ISAKSON, Mr. WYDEN, Mr. BURR, Mr. DODD, Ms. SNOWE, Mr. SANDERS, Mr. HATCH, Ms. CANTWELL, Mr. CARDIN, Mr. SCHUMER, Mrs. CLINTON, Ms. MIKULSKI, and Mrs. LINCOLN) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend part B of title XVIII of the Social Security Act to delay and reform the Medicare competitive acquisition program for purchase of durable medical equipment, prosthetics, orthotics, and supplies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare DMEPOS
5 Competitive Acquisition Reform Act of 2008”.

1 **SEC. 2. DELAY IN AND REFORM OF MEDICARE DMEPOS**
 2 **COMPETITIVE ACQUISITION PROGRAM.**

3 (a) TEMPORARY DELAY AND REFORM.—

4 (1) IN GENERAL.—Section 1847(a)(1) of the
 5 Social Security Act (42 U.S.C. 1395w-3(a)(1)) is
 6 amended—

7 (A) in paragraph (1)—

8 (i) in subparagraph (B)(i), in the
 9 matter before subclause (I), by inserting
 10 “consistent with subparagraph (D)” after
 11 “in a manner”;

12 (ii) in subparagraph (B)(i)(II), by
 13 striking “80” and “in 2009” and inserting
 14 “an additional 70” and “in 2011”, respec-
 15 tively;

16 (iii) in subparagraph (B)(i)(III), by
 17 striking “after 2009” and inserting “after
 18 2011 (or, in the case of national mail order
 19 for items and services, after 2010)”; and

20 (iv) by adding at the end the following
 21 new subparagraphs:

22 “(D) CHANGES IN COMPETITIVE ACQUISITION PROGRAMS.—

24 “(i) ROUND 1 OF COMPETITIVE AC-
 25QUISITION PROGRAM.—Notwithstanding
 26 subparagraph (B)(i)(I) and in imple-

1 menting the first round of the competitive
2 acquisition programs under this section—

3 “(I) the contracts awarded under
4 this section before the date of the en-
5 actment of this subparagraph are ter-
6 minated, no payment shall be made
7 under this title on or after the date of
8 the enactment of this subparagraph
9 based on such a contract, and, to the
10 extent that any damages may be ap-
11 plicable as a result of the termination
12 of such contracts, such damages shall
13 be payable from the Federal Supple-
14 mentary Medical Insurance Trust
15 Fund under section 1841;

16 “(II) the Secretary shall conduct
17 the competition for such round in a
18 manner so that it occurs in 2009 with
19 respect to the same items and services
20 and the same areas, except as pro-
21 vided in subclauses (III) and (IV);

22 “(III) the Secretary shall exclude
23 Puerto Rico so that such round of
24 competition covers 9, instead of 10, of

1 the largest metropolitan statistical
2 areas; and

3 “(IV) there shall be excluded
4 negative pressure wound therapy
5 items and services.

6 Nothing in subclause (I) shall be construed
7 to provide an independent cause of action
8 or right to administrative or judicial review
9 with regard to the termination provided
10 under such subclause.

11 “(ii) ROUND 2 OF COMPETITIVE AC-
12 QUISSION PROGRAM.—In implementing
13 the second round of the competitive acqui-
14 sition programs under this section de-
15 scribed in subparagraph (B)(i)(II)—

16 “(I) the metropolitan statistical
17 areas to be included shall be those
18 metropolitan statistical areas selected
19 by the Secretary for such round as of
20 June 1, 2008; and

21 “(II) the Secretary may sub-
22 divide metropolitan statistical areas
23 with populations (based upon the
24 most recent data from the Census Bu-
25 reau) of at least 8,000,000 into sepa-

rate areas for competitive acquisition purposes.

“(iii) EXCLUSION OF CERTAIN AREAS IN SUBSEQUENT ROUNDS OF COMPETITIVE ACQUISITION PROGRAMS.—In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

“(I) Rural areas.

“(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

“(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

“(E) VERIFICATION BY OIG.—The Inspector General of the Department of Health and Human Services shall, through post-award

1 audit, survey, or otherwise, assess the process
2 used by the Centers for Medicare & Medicaid
3 Services to conduct competitive bidding and
4 subsequent pricing determinations under this
5 section that are the basis for pivotal bid
6 amounts and single payment amounts for items
7 and services in competitive bidding areas under
8 rounds 1 and 2 of the competitive acquisition
9 programs under this section and may continue
10 to verify such calculations for subsequent
11 rounds of such programs.

12 “(F) SUPPLIER FEEDBACK ON MISSING FI-
13 NANCIAL DOCUMENTATION.—

14 “(i) IN GENERAL.—In the case of a
15 bid where one or more covered documents
16 in connection with such bid have been sub-
17 mitted not later than the covered document
18 review date specified in clause (ii), the Sec-
19 retary—

20 “(I) shall provide, by not later
21 than 45 days (in the case of the first
22 round of the competitive acquisition
23 programs as described in subpara-
24 graph (B)(i)(I)) or 90 days (in the
25 case of a subsequent round of such

1 programs) after the covered document
2 review date, for notice to the bidder of
3 all such documents that are missing
4 as of the covered document review
5 date; and

6 “(II) may not reject the bid on
7 the basis that any covered document
8 is missing or has not been submitted
9 on a timely basis, if all such missing
10 documents identified in the notice pro-
11 vided to the bidder under subclause
12 (I) are submitted to the Secretary not
13 later than 10 business days after the
14 date of such notice.

15 “(ii) COVERED DOCUMENT REVIEW
16 DATE.—The covered document review date
17 specified in this clause with respect to a
18 competitive acquisition program is the
19 later of—

20 “(I) the date that is 30 days be-
21 fore the final date specified by the
22 Secretary for submission of bids
23 under such program; or

24 “(II) the date that is 30 days
25 after the first date specified by the

1 Secretary for submission of bids
2 under such program.

3 “(iii) LIMITATIONS OF PROCESS.—

4 The process provided under this subpara-
5 graph—

6 “(I) applies only to the timely
7 submission of covered documents;

8 “(II) does not apply to any deter-
9 mination as to the accuracy or com-
10 pleteness of covered documents sub-
11 mitted or whether such documents
12 meet applicable requirements;

13 “(III) shall not prevent the Sec-
14 retary from rejecting a bid based on
15 any basis not described in clause
16 (i)(II); and

17 “(IV) shall not be construed as
18 permitting a bidder to change bidding
19 amounts or to make other changes in
20 a bid submission.

21 “(iv) COVERED DOCUMENT DE-
22 FINED.—In this subparagraph, the term
23 ‘covered document’ means a financial, tax,
24 or other document required to be sub-
25 mitted by a bidder as part of an original

bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.”; and

(B) in paragraph (2)(A), by inserting before the period at the end the following: “and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs)”.

(2) BUDGET NEUTRAL OFFSET.—

(A) IN GENERAL.—Section 1834(a)(14) of such Act (42 U.S.C. 1395m(a)(14)) is amended—

(i) by striking “and” at the end of subparagraphs (H) and (I);

(ii) by redesignating subparagraph (J) as subparagraph (M); and

(iii) by inserting after subparagraph (I) the following new subparagraphs:

“(J) for 2009—

1 “(i) in the case of items and services
2 furnished in any geographic area, if such
3 items or services were selected for competi-
4 tive acquisition in any area under the com-
5 petitive acquisition program under section
6 1847(a)(1)(B)(i)(I) before July 1, 2008,
7 including diabetic supplies but only if fur-
8 nished through mail order, - 9.5 percent;
9 or

10 “(ii) in the case of other items and
11 services, the percentage increase in the
12 consumer price index for all urban con-
13 sumers (U.S. urban average) for the 12-
14 month period ending with June 2008;

15 “(K) for 2010, 2011, 2012, and 2013, the
16 percentage increase in the consumer price index
17 for all urban consumers (U.S. urban average)
18 for the 12-month period ending with June of
19 the previous year;

20 “(L) for 2014—

21 “(i) in the case of items and services
22 described in subparagraph (J)(i) for which
23 a payment adjustment has not been made
24 under subsection (a)(1)(F)(ii) in any pre-
25 vious year, the percentage increase in the

1 consumer price index for all urban con-
2 sumers (U.S. urban average) for the 12-
3 month period ending with June 2013, plus
4 2.0 percentage points; or

5 “(ii) in the case of other items and
6 services, the percentage increase in the
7 consumer price index for all urban con-
8 sumers (U.S. urban average) for the 12-
9 month period ending with June 2013;
10 and”.

11 (B) CONFORMING TREATMENT FOR CER-
12 TAIN ITEMS AND SERVICES.—The second sen-
13 tence of section 1842(s)(1) of such Act (42
14 U.S.C. 1395u(s)(1)) is amended by striking
15 “except that” and all that follows and inserting
16 the following: “except that for items and serv-
17 ices described in paragraph (2)(D)—

18 “(A) for 2009 section 1834(a)(14)(J)(i) shall
19 apply under this paragraph instead of the percent-
20 age increase otherwise applicable; and

21 “(B) for 2014, if subparagraph (A) applied to
22 the items and services and there has not been a pay-
23 ment adjustment under subsection (h)(1)(H) for the
24 items and services for any previous year, the per-
25 centage increase computed under section

1 1834(a)(14)(L)(i) shall apply instead of the percent-
 2 age increase otherwise applicable.”.

3 (3) CONFORMING DELAY.—Subsections
 4 (a)(1)(F) and (h)(1)(II) of section 1834 of the So-
 5 cial Security Act (42 U.S.C. 1395m) are each
 6 amended by striking “January 1, 2009” and insert-
 7 ing “January 1, 2011”.

8 (4) CONSIDERATIONS IN APPLICATION.—Sec-
 9 tion 1834 of such Act (42 U.S.C. 1395m) is amend-
 10 ed—

11 (A) in subsection (a)(1)—

12 (i) in subparagraph (F), by inserting
 13 “subject to subparagraph (G),” before
 14 “that are included”; and

15 (ii) by adding at the end the following
 16 new subparagraph:

17 “(G) USE OF INFORMATION ON COMPETI-
 18 TIVE BID RATES.—The Secretary shall specify
 19 by regulation the methodology to be used in ap-
 20 plying the provisions of subparagraph (F)(ii)
 21 and subsection (h)(1)(II)(ii). In promulgating
 22 such regulation, the Secretary shall consider the
 23 costs of items and services in areas in which
 24 such provisions would be applied compared to

the payment rates for such items and services in competitive acquisition areas.”; and

(B) in subsection (h)(1)(H), by inserting “subject to subsection (a)(1)(G),” before “that are included”.

(b) QUALITY STANDARDS.—

(1) APPLICATION OF ACCREDITATION REQUIREMENT.—

(A) IN GENERAL.—Section 1834(a)(20) of the Social Security Act (42 U.S.C. 1395m(a)(20)) is amended—

(i) in subparagraph (E), by inserting “including subparagraph (F),” after “under this paragraph,”; and

(ii) by adding at the end the following new subparagraph:

“(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

“(i) subject to clause (ii), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary

1 evidence of accreditation by an accredita-
2 tion organization designated under sub-
3 paragraph (B) as meeting applicable qual-
4 ity standards; and

5 “(ii) in applying such standards and
6 the accreditation requirement of clause (i)
7 with respect to eligible professionals (as
8 defined in section 1848(k)(3)(B)), and in-
9 cluding such other persons, such as
10 orthotists and prosthetists, as specified by
11 the Secretary, furnishing such items and
12 services—

13 “(I) such standards and accredi-
14 tation requirement shall not apply to
15 such professionals and persons unless
16 the Secretary determines that the
17 standards being applied are designed
18 specifically to be applied to such pro-
19 fessionals and persons; and

20 “(II) the Secretary may exempt
21 such professionals and persons from
22 such standards and requirement if the
23 Secretary determines that licensing,
24 accreditation, or other mandatory
25 quality requirements apply to such

professionals and persons with respect
to the furnishing of such items and
services.”.

(B) CONSTRUCTION.—Section
1834(a)(20)(F)(ii) of the Social Security Act,
as added by subparagraph (A), shall not be con-
strued as preventing the Secretary of Health
and Human Services from implementing the
first round of competition under section 1847
of such Act on a timely basis.

(2) DISCLOSURE OF SUBCONTRACTORS UNDER
COMPETITIVE ACQUISITION PROGRAM.—Section
1847(b)(3) of such Act (42 U.S.C. 1395w-3(b)(3))
is amended by adding at the end the following new
subparagraph:

“(C) DISCLOSURE OF SUBCONTRACTORS.—

“(i) INITIAL DISCLOSURE.—Not later
than 10 days after the date a supplier en-
ters into a contract with the Secretary
under this section, such supplier shall dis-
close to the Secretary, in a form and man-
ner specified by the Secretary, the infor-
mation on—

1 “(I) each subcontracting relation-
 2 ship that such supplier has in fur-
 3 nishing items and services under the
 4 contract; and

5 “(II) whether each such subcon-
 6 tractor meets the requirement of sec-
 7 tion 1834(a)(20)(F)(i), if applicable
 8 to such subcontractor.

9 “(ii) SUBSEQUENT DISCLOSURE.—Not
 10 later than 10 days after such a supplier
 11 subsequently enters into a subcontracting
 12 relationship described in clause (i)(II),
 13 such supplier shall disclose to the Sec-
 14 retary, in such form and manner, the in-
 15 formation described in subclauses (I) and
 16 (II) of clause (i).”.

17 (3) COMPETITIVE ACQUISITION OMBUDSMAN.—

18 Such section is further amended by adding at the
 19 end the following new subsection:

20 “(f) COMPETITIVE ACQUISITION OMBUDSMAN.—The
 21 Secretary shall provide for a competitive acquisition om-
 22 budsman within the Centers for Medicare & Medicaid
 23 Services in order to respond to complaints and inquiries
 24 made by suppliers and individuals relating to the applica-
 25 tion of the competitive acquisition program under this sec-

1 tion. The ombudsman may be within the office of the
 2 Medicare Beneficiary Ombudsman appointed under sec-
 3 tion 1808(c). The ombudsman shall submit to Congress
 4 an annual report on the activities under this subsection,
 5 which report shall be coordinated with the report provided
 6 under section 1808(c)(2)(C).”.

7 (c) CHANGE IN REPORTS AND DEADLINES.—

8 (1) GAO REPORT.—Section 302(b)(3) of the
 9 Medicare Prescription Drug, Improvement, and
 10 Modernization Act of 2003 (Public Law 108–173) is
 11 amended—

12 (A) in subparagraph (A)—

13 (i) by inserting “and as amended by
 14 section 2 of the Medicare DMEPOS Com-
 15 petitive Acquisition Reform Act of 2008”
 16 after “as amended by paragraph (1)”;

17 (ii) by inserting before the period at
 18 the end the following: “and the topics spec-
 19 ified in subparagraph (C)”;

20 (B) in subparagraph (B), by striking “Not
 21 later than January 1, 2009,” and inserting
 22 “Not later than 1 year after the first date that
 23 payments are made under section 1847 of the
 24 Social Security Act,”; and

1 (C) by adding at the end the following new
2 subparagraph:

3 “(C) TOPICS.—The topics specified in this
4 subparagraph, for the study under subpara-
5 graph (A) concerning the competitive acquisi-
6 tion program, are the following:

7 “(i) Beneficiary access to items and
8 services under the program, including the
9 impact on such access of awarding con-
10 tracts to bidders that—

11 “(I) did not have a physical pres-
12 ence in an area where they received a
13 contract; or

14 “(II) had no previous experience
15 providing the product category they
16 were contracted to provide.

17 “(ii) Beneficiary satisfaction with the
18 program and cost savings to beneficiaries
19 under the program.

20 “(iii) Costs to suppliers of partici-
21 pating in the program and recommenda-
22 tions about ways to reduce those costs
23 without compromising quality standards or
24 savings to the Medicare program.

1 “(iv) Impact of the program on small
2 business suppliers.

3 “(v) Analysis of the impact on utiliza-
4 tion of different items and services paid
5 within the same Healthcare Common Pro-
6 cedure Coding System (HCPCS) code.

7 “(vi) Costs to the Centers for Medi-
8 care & Medicaid Services, including pay-
9 ments made to contractors, for admin-
10 istering the program compared with ad-
11 ministration of a fee schedule, in compari-
12 son with the relative savings of the pro-
13 gram.

14 “(vii) Impact on access, Medicare
15 spending, and beneficiary spending of any
16 difference in treatment for diabetic testing
17 supplies depending on how such supplies
18 are furnished.

19 “(viii) Such other topics as the Comp-
20 troller General determines to be appro-
21 priate.”.

22 (2) DELAY IN OTHER DEADLINES.—

23 (A) PROGRAM ADVISORY AND OVERSIGHT
24 COMMITTEE.—Section 1847(c)(5) of the Social
25 Security Act (42 U.S.C. 1395w-3(c)(5)) is

1 amended by striking “December 31, 2009” and
2 inserting “December 31, 2011”.

3 (B) SECRETARIAL REPORT.—Section
4 1847(d) of such Act (42 U.S.C. 1395w–3(d)) is
5 amended by striking “July 1, 2009” and insert-
6 ing “July 1, 2011”.

7 (C) IG REPORT.—Section 302(e) of the
8 Medicare Prescription Drug, Improvement, and
9 Modernization Act of 2003 (Public Law 108–
10 173) is amended by striking “July 1, 2009”
11 and inserting “July 1, 2011”.

12 (3) EVALUATION OF CERTAIN CODE.—The Sec-
13 retary of Health and Human Services shall evaluate
14 the existing Healthcare Common Procedure Coding
15 System (HCPCS) code for negative pressure wound
16 therapy to ensure accurate reporting and billing for
17 items and services under such code. In carrying out
18 such evaluation, the Secretary shall use the existing
19 process for the consideration of coding changes and
20 consider all relevant studies and information fur-
21 nished pursuant to such process.

22 (d) OTHER PROVISIONS.—

23 (1) EXEMPTION FROM COMPETITIVE ACQUISI-
24 TION FOR CERTAIN OFF-THE-SHELF ORTHOTICS.—
25 Section 1847(a) of the Social Security Act (42

1 U.S.C. 1395w-3(a)) is amended by adding at the
2 end the following new paragraph:

3 “(7) EXEMPTION FROM COMPETITIVE ACQUISITION.—The programs under this section shall not
4 apply to the following:

6 “(A) CERTAIN OFF-THE-SHELF
7 ORTHOTICS.—Items and services described in
8 paragraph (2)(C) if furnished—

9 “(i) by a physician or other practi-
10 tioner (as defined by the Secretary) to the
11 physician’s or practitioner’s own patients
12 as part of the physician’s or practitioner’s
13 professional service; or

14 “(ii) by a hospital to the hospital’s
15 own patients during an admission or on
16 the date of discharge.

17 “(B) CERTAIN DURABLE MEDICAL EQUIP-
18 MENT.—Those items and services described in
19 paragraph (2)(A)—

20 “(i) that are furnished by a hospital
21 to the hospital’s own patients during an
22 admission or on the date of discharge; and

23 “(ii) to which such programs would
24 not apply, as specified by the Secretary, if
25 furnished by a physician to the physician’s

own patients as part of the physician's professional service.”.

(2) CORRECTION IN FACE-TO-FACE EXAMINATION REQUIREMENT.—Section 1834(a)(1)(E)(ii) of such Act (42 U.S.C. 1395m(a)(1)(E)(ii)) is amended by striking “1861(r)(1)” and inserting “1861(r)”.

(3) SPECIAL RULE IN CASE OF NATIONAL MAIL-ORDER COMPETITION FOR DIABETIC TESTING STRIPS.—Section 1847(b) of such Act (42 U.S.C. 1395w-3(b)) is amended—

(A) by redesignating paragraph (10) as paragraph (11); and

(B) by inserting after paragraph (9) the following new paragraph:

“(10) SPECIAL RULE IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.—

“(A) IN GENERAL.—With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the

1 Secretary may specify) of all such types of
2 products, the Secretary shall reject such bid.
3 The volume for such types of products may be
4 determined in accordance with such data (which
5 may be market based data) as the Secretary
6 recognizes.

7 “(B) STUDY OF TYPES OF TESTING STRIP
8 PRODUCTS.—Before 2011, the Inspector Gen-
9 eral of the Department of Health and Human
10 Services shall conduct a study to determine the
11 types of diabetic testing strip products by vol-
12 ume that could be used to make determinations
13 pursuant to subparagraph (A) for the first com-
14 petition under the competitive acquisition pro-
15 gram described in such subparagraph and sub-
16 mit to the Secretary a report on the results of
17 the study. The Inspector General shall also con-
18 duct such a study and submit such a report be-
19 fore the Secretary conducts a subsequent com-
20 petitive acquisition program described in sub-
21 paragraph (A).”.

22 (4) OTHER CONFORMING AMENDMENTS.—Sec-
23 tion 1847(b)(11) of such Act, as redesignated by
24 paragraph (3), is amended—

1 (A) in subparagraph (C), by inserting “and
 2 the identification of areas under subsection
 3 (a)(1)(D)(iii)” after “(a)(1)(A)”;

4 (B) in subparagraph (D), by inserting
 5 “and implementation of subsection (a)(1)(D)”
 6 after “(a)(1)(B)”;

7 (C) in subparagraph (E), by striking “or”
 8 at the end;

9 (D) in subparagraph (F), by striking the
 10 period at the end and inserting “; or”; and

11 (E) by adding at the end the following new
 12 subparagraph:

13 “(G) the implementation of the special rule
 14 described in paragraph (10).”.

15 (5) FUNDING FOR IMPLEMENTATION.—In addi-
 16 tion to funds otherwise available, for purposes of im-
 17 plementing the provisions of, and amendments made
 18 by, this section, other than the amendment made by
 19 subsection (c)(1) and other than section
 20 1847(a)(1)(E) of the Social Security Act, the Sec-
 21 retary of Health and Human Services shall provide
 22 for the transfer from the Federal Supplementary
 23 Medical Insurance Trust Fund established under
 24 section 1841 of the Social Security Act (42 U.S.C.
 25 1395t) to the Centers for Medicare & Medicaid Serv-

1 ices Program Management Account of \$20,000,000
2 for fiscal year 2008, and \$25,000,000 for each of
3 fiscal years 2009 through 2012. Amounts trans-
4 ferred under this paragraph for a fiscal year shall be
5 available until expended.

6 (e) EFFECTIVE DATE.—The amendments made by
7 this section shall take effect as of June 30, 2008.

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